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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Derek Muehrcke. Doc. 7304. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard IVC filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

The parties intend to use various expert witnesses at trial, including medical professionals. Plaintiffs have identified Dr. Muehrcke, a cardiothoracic surgeon, as an expert witness on various issues in each of the five cases selected for bellwether trials. He has prepared case-specific reports that share certain opinions in common. Doc. 7307. Defendants ask the Court to exclude seven categories of opinions: (1) Bard filters have design defects; (2) adoption of opinions of other experts; (3) reasonable expectations of physicians regarding filter performance; (4) Bard filters have an "unacceptable" risk of caudal migration; (5) Bard acted unethically in selling its filters; (6) Bard's state of mind, motive, and intent; and (7) the failure of Plaintiff Lisa Hyde's filter resulted in an increased risk for arrhythmias and sudden death, and the need for an implantable defibrillator. Doc. 7304 at 2.[1] The Court will address each category.[2]

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v.*

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[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

[2] The bellwether cases are those brought by Plaintiffs Sherr-Una Booker, Lisa Hyde, Doris Jones, Carol Kruse, and Debra Mulkey.

Merrell Dow Pharm., Inc., 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Design Defects.

Dr. Muehrcke is a cardiothoracic surgeon who received his specialty training at Harvard Medical School and Massachusetts General Hospital. Doc. 7307 at 2. He serves as Chief of Cardiothoracic Surgery at Flagler Hospital in St. Augustine, Florida, and is part of a private medical group that performs heart surgeries at seven area hospitals. *Id.* at 3. He implants or removes nearly 50 IVC filters per year, and has more than 20 years' experience treating patients with IVC filters. *Id.* at 2-3.

Defendants argue that Dr. Muehrcke is not qualified to offer design related opinions because he has never designed or tested an IVC filter and has no background in engineering, metallurgy, or materials science. Doc. 7304 at 3. Defendants ask the Court to exclude this design opinion:

> Due to the filters [sic] inadequate design, Ms. Booker's filter tilted, became embedded in the vena cava, punctured through the vena cava and surrounding organs and structures, multiple strut fractures occurred, and filter fragments embolized to the heart. Specifically, the device's inadequate migration resistance, and lack of strength and stability, caused by its weak anchoring hooks and lack of radial force and inadequate leg span to accommodate vessel distention were substantial factors in causing this device to migrate in a caudal direction, tilt, perforate the vena cava, and fracture. In reaching this opinion, I reviewed Ms. Booker's medical records and radiology, and performed a differential diagnosis, and there is no other reasonable cause for the failures of the filter.

Doc. 7307 at 10. Dr. Muehrcke offers similar opinions in other bellwether cases. *See* Docs. 7307-1 at 9 (inadequate migration resistance and lack of strength and stability

caused Plaintiff Hyde's G2 filter to migrate, tilt, perforate the IVC, and fracture); 7307-2 at 9 (lack of strength and stability caused Plaintiff Jones's Eclipse filter to fracture); 7307-3 at 9 (inadequate migration resistance and lack of strength and stability caused Plaintiff Kruse's G2 filter to migrate, tilt, and fracture).

The quoted opinion states that several specific structural characteristics of the G2 filter were substantial factors in causing it to migrate, tilt, perforate the IVC, and fracture. These include the filter's inadequate migration resistance and lack of strength and stability caused by its (1) weak anchoring hooks, (2) lack of radial force, and (3) inadequate leg span. Doc. 7307 at 10. Clearly, Dr. Muehrcke is not qualified to testify about anchoring hooks, radial force, or leg span as an engineer, metallurgist, or product designer – he claims none of those qualifications. Thus, to the extent Plaintiffs offer his testimony as a design or engineering expert on characteristics of IVC filters, he is not qualified and will be excluded.

But Dr. Muehrcke identifies a different basis for his opinion: "In reaching this opinion, I reviewed Ms. Booker's medical records and radiology, and performed a differential diagnosis, and there is no other reasonable cause for the failures of the filter." *Id.* In other words, he reviewed Booker's medical records and the x-rays of her filter and, as a thoracic surgeon with years of experience in implanting and removing IVCs, could find no other cause for the failure of her Bard filter than inadequate migration resistance. Dr. Muehrcke is qualified to give this opinion. As a trained and experienced thoracic surgeon who regularly uses IVC filters and engages in differential diagnoses, he is qualified to opine on factors that caused a filter's failure – in this case, an inability to resist migration in the IVC. Whether he can also opine on more specific design problems such as a lack of strength and stability caused by weak anchoring hooks, lack of radial force, and inadequate leg span depends on whether his medical training and experience provides expertise on these specific aspects of IVC filters, something the Court cannot determine on this record.

The Court will permit Dr. Muehrcke to opine that Ms. Booker's problems arose because the Bard filter's design had inadequate migration resistance. Whether he can provide more specific testimony on the cause of this inadequacy will depend on the foundation laid at trial.

B. Reliance on Other Expert Reports.

Defendants contend that Dr. Muehrcke's opinions are unreliable because he adopts the opinions of Drs. Kinney, Kalva, Roberts, and Eisenberg. Doc. 7304 at 5-6. As the Court previously has found, Rule 703 permits experts to rely on opinions of other experts. *See* Doc. 9434 at 3-4 (citing *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013); *E. Allen Reeves, Inc. v. Michael Graves & Assocs., Inc.*, No. 10-1393 (MAS), 2015 WL 105825, at *5 (D.N.J. Jan. 7, 2015); *Eaves v. United States*, No. 4:07-CV-118-M, 2009 WL 3754176, at *9 (W.D. Ky. Nov. 5, 2009)). Neither Dr. Muehrcke nor any other expert will be permitted at trial to simply parrot the opinions of other experts, or to vouch for those experts, but they can rely on opinions stated by other experts.

C. Opinions Regarding the Reasonable Expectations of Physicians.

Dr. Muehrcke offers this opinion in the Booker case:

> Based upon the information available to Bard at the time the filter was implanted in Ms. Booker, it was clear that the risks of the Bard . . . filter exceeded its benefits and that this filter did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard.
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> In using Bard's . . . filter, physicians reasonably expected that if the filter was properly placed it would not migrate, tilt, perforate the vena cava and adjacent organs/structures, fracture, or have filter fragments embolize to the heart. In my opinion, because this filter failed in the manner previously described, Ms. Booker was exposed to risks that exceeded any benefits allegedly offered by this particular filter nor would a physician or patient reasonably expect this constellation of failure modes to occur.

Doc. 7307 at 10. Similar opinions are rendered in the other bellwether cases. *See* Docs. 7307-1 – 7307-3 at 9; 7307-4 at 8.

Defendants ask the Court to exclude these opinions on the ground that Dr. Muehrcke cannot speak on behalf of all physicians regarding reasonable expectations of IVC filters. Docs. 7304 at 6-8; 8224 at 7-10. Defendants claim that Dr. Muehrcke is not qualified to offer such opinions and has identified no reliable methodology, noting that he cites no supporting scientific literature, has conducted no survey as to what other physicians think, and acknowledges that the risk-benefit analysis performed by individual physicians is a subjective art form, not a science. *Id*.

Plaintiffs assert that Dr. Muehrcke is not purporting to speak on behalf of other physicians, but instead is offering an opinion about the adequacy of Bard's warnings. Doc. 7813 at 10. Plaintiffs state that in "giving the opinion that the Bard G2 filter 'did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard,' Dr. Muehrcke is clearly opining that the warnings and other information provided by Bard to physicians was insufficient." *Id.* at 10-11 (quoting Doc. 7307-1 at 9). Plaintiffs further state that "Dr. Muehrcke's opinion – which expressly mentions 'the manner represented by Bard' – is an opinion that Bard did not provide physicians with adequate information about the risks presented by its IVC filters." *Id.* at 11. Plaintiffs conclude by stating that based on his extensive experience implanting and removing IVC filters, Dr. Muehrcke's "warnings opinions" are reliable. *Id.* at 12.

Given this response and Plaintiffs' focus on Dr. Muehrcke's "warnings opinions," it is not clear whether Plaintiffs intend to have Dr. Muehrcke testify at trial about the reasonable expectations of physicians regarding filter performance. He clearly expresses such opinions in each report. *See, e.g.*, Doc. 7307 at 10. He also opines in each report that "the risks of the Bard . . . filter exceeded its benefits" and that each Plaintiff "was exposed to risks that exceeded any benefits allegedly offered by [their] particular filter." *See id.* Plaintiffs do not address these risk-benefit opinions in their response brief.

The admissibility of similar opinions was addressed in a recent order concerning Drs. Kinney, Roberts, and Kalva. Doc. 9434. Given the doctors' qualifications and

experience as interventional radiologists, the Court found that they should not be precluded from testifying about what disclosures reasonable physicians expect to receive from manufacturers of IVC filters. *Id.* at 6-9. With respect to testimony about what physicians would have done with additional information, however, the Court concluded that the admissibility of such testimony must be determined at trial. *Id.* at 9.

The Court reaches similar conclusions regarding Dr. Muehrcke. Defendants do not dispute that Dr. Muehrcke is a well-qualified cardiothoracic surgeon. During the past 20 years, he has implanted and removed hundreds of IVC filters, including those manufactured by Bard. Doc. 7307 at 2-3. Under Rule 702 and *Daubert*, expert testimony "is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565 (citation omitted). The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his opinion as to the information reasonable physicians expect to receive from IVC manufacturers, and whether physicians who implant IVC filters reasonably expect a properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring organs. Defendants may, of course, challenge the reliability of these opinions through cross examination or qualified experts of their own.

Dr. Muehrcke's risk-benefit opinions are more problematic. Whether the risks of using a particular medical device outweigh the benefits is a fact- and patient-specific decision not amenable to broad generalizations about what a "reasonable" patient or physician would decide. The propriety of testimony on this subject will depend heavily on the context and relevancy of the question. The Court will make these rulings during trial.

D. Opinions on the "Unacceptable" Risk of Migration.

In his report for the Booker case, Dr. Muehrcke offers this opinion regarding the G2 filter's migration risk:

> Bard had been aware since late 2005/early 2006 of the need to correct the "unacceptable" caudal migration risk with the G2 filter. Bard was also aware that caudal migration leads to tilt, perforation, penetration,

> irretrievability, and fracture. Despite this knowledge, Bard did nothing to inform physicians or patients of these safety risks; choosing instead to launch two more filters, the G2X and Eclipse, prior to launching a filter, the Meridian, that addresses caudal migration. Ms. Booker's filter ultimately failed in the manners expected of the G2 filter – e.g., caudal migration, tilt, irretrievability, perforation/penetration, and fracture – which the Meridian was intended to correct. In my opinion, Bard should have removed the G2 filter from the medical market and medical facilities given its knowledge of the "unacceptable" risk of caudal migration[.]

Doc. 7307 at 8. Similar opinions are set forth in the reports for two other bellwether cases. *See* Docs. 7307-1 at 8 (Hyde), 7307-2 at 8-9 (Jones).[3]

The Court concludes that Dr. Muehrcke should not be permitted to opine on Bard filter failure rates. Even if a physician could be qualified to render such opinions, he has not conducted any study of IVC filter complication rates. Plaintiffs argue that his opinions are based on personal experience with IVC filters and his training and experience as a doctor, but he does not state that he tracked failure rates in his personal cases. Dr. Muehrcke did review a number of medical articles regarding IVC filter complication rates, including the Deso article, which concerned a literature search regarding complications associated with various IVC filter designs. Doc. 7302-2.[4] But even if these articles suggest that Bard filters have higher complication rates than other filters, Dr. Muehrcke does not claim to have taken any steps to verify their conclusions, and merely restating those conclusions does not constitute a reliable basis for rendering an expert opinion under Rule 702. Dr. Muehrcke cannot simply repeat the opinions of others as his own when he has done nothing to verify the accuracy of the opinions. *See In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of

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[3] Defendants assert that this opinion also is included in the report for the Mulkey case (Doc. 7304 at 12), but the cited page is not included in the copy of the report filed with the Court (see Doc. 7307-4 at 7-8).

[4] The article is "Evidence-Based Evaluation of [IVC] Filter Complications Based on Filter Type," co-authored by Drs. Steven Deso, Ibrahim Idakoji, and William Kuo, and published in *Seminars in Interventional Radiology* (Vol. 33 at 93-100, No. 2/2016).

other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

His opinion that the G2 filter poses an "unacceptable risk" of caudal migration is based on a Bard internal document. A report titled "G2 Caudal Migration Update," prepared by Bard product quality engineer Natalie Wong, states that in certain circumstances the G2 filter had an "[u]nacceptable risk" of caudal migration per Bard's failure modes and effects analysis. Doc. 7825 at 21. Again, however, Dr. Muehrcke does not identify any steps he has taken to verify the conclusion in the Wong report. Nor does he identify the person or entity to whom the risk he mentions is unacceptable – physicians, patients, medical manufacturers, the FDA, etc. Indeed, in his deposition he steadfastly refused to identify an acceptable failure rate, saying only that it should be as close to zero as possible. Doc. 7304 at 10 (quoting Dep. Tr. 65:2-5).

Dr. Muehrcke could opine, as a treating physician who must make decisions about IVC filter use, that Bard should have disclosed any risks it found in its products that would be unacceptable to doctors and patients. But he cannot opine that Bard filters present an "unacceptable risk" unless that opinion is based on sufficient facts and data he has identified, to which he has applied reliable principles and methods. Fed. R. Evid. 702(b), (c). Merely repeating conclusions in the Wong report as his own opinion does not meet this requirement.

Nor can Dr. Muehrcke opine about the failure rates of Eclipse filters. Plaintiffs identify no study or articles he reviewed on Eclipse failure rates, much less any he verified.

E. Opinions Regarding State of Mind and Ethics.

Defendants argue that Dr. Muehrcke's opinions about what Bard knew or should have done, and Bard's underlying motives and intent, are classic jury questions outside the bounds of appropriate expert testimony. Doc. 7304 at 12-13. Plaintiffs state that the doctor will not opine as to motives or intent, but contend that the degree of Bard's

knowledge about the dangers posed by its filters is relevant to the failure-to-warn claims. Doc. 7813 at 17-18.

Dr. Muehrcke will not be permitted to opine about Bard's knowledge, intent, or ethics. *See* Doc. 9434 at 17. He does not purport to be an expert on corporate information processing and he has not conducted any study of Bard internal operations, information gathering, or corporate ethics. Plaintiffs propose to have him opine about what Bard knew based on selected documents, but identify no expertise that enables him to opine on Bard's knowledge. Dr. Muehrcke may opine that Bard should have provided warnings to physicians and patients if it knew of excess risks, but it will be up to other evidence to show that Bard had such knowledge.

F. Opinions on the Future Medical Risks and Needs in the Hyde Case.

Dr. Muehrcke opines that as a result of the failure of Plaintiff Hyde's G2 filter, she is at risk for arrhythmias and sudden death, and will need an implantable defibrillator. Doc. 7307-1 at 8-9. Defendants challenge this opinion on the ground that Dr. Muehrcke cannot quantify the future medical risks and needs. Doc. 7304 at 13-14. The Court concludes that it will be better able to address this issue in the context of the Hyde trial and after trying a few bellwether cases, and therefore will withhold ruling until the Hyde case is ready for trial. Defendants may reassert their arguments in a motion in limine.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Derek Muehrcke (Doc. 7304) is **granted in part** and **denied in part** as set forth in this order.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge